



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

4349 01 MAY 15 P 2:30

MAY - 1 2001

Mr. Ralph Fucetola III, J.D.
Goen Group/Goen Corporation
8 Ridgedale Avenue
Cedar Knolls, New Jersey 07927

Dear Mr. Fucetola:

This is in response to your letter of April 12, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission responds to our letter dated March 7, 2001 in which FDA advised you that certain claims being made for your products appeared to be disease claims under the Act.

In your current submission, you included additional claims that you intend to make for your product Trim Spa™ that were not a part of your earlier submission for this product. Your current submission states that Goen Group/Goen Corporation is making the following claims, among others, for this product:

“...helpful in reducing weight caused by thyroid troubles”
“Helps in many stomach problems such as irritable bowel syndrome,
nausea...diarrhea, constipation...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate diseases, namely thyroid disorders and gastrointestinal diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

97S 0163

LET 488

Page 2 - Mr. Ralph Fucetola III

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA240

Page 3 - Mr. Ralph Fucetola III

cc:

HFA-224

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-8 10 (Foret)

HFS-8 11 (Moore, w/original incomingfile)

HFD-40 (Behrman)

HFD-3 10

HFD-3 14 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson) ,

f/t:04/25/00:docname:goen.adv:disc56

GOEN GROUP

GOEN CORPORATION

8 Ridgedale Avenue
Cedar Knolls, NJ 07927

973-267-4400 x 4020

Fax 973-267-5506

LEGAL DEPARTMENT

Ralph Fucetola III, JD
Corporate Counsel
ralph.fucetola@goengroup.com

75601

Goen Technologies Corporation
Vitamerica Corporation
A. Goen Seminars Institute, Inc.
Seminar Helpers, L.L.C.
Nutramerica Corporation
Health Sciences Direct
Weight Loss Labs

TRANSMITTAL MEMORANDUM

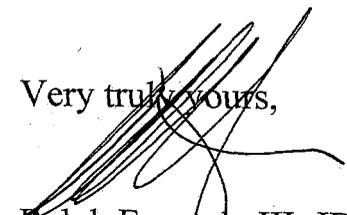
April 12, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Gentlepeople,

Herewith we enclose three revised 21 U.S.C. 403(r)(6) Notices of Statements with a copy of a letter to the Director of the Division of Compliance and Enforcement.

Very truly yours,


Ralph Fucetola III, JD

ENC.

GOEN GROUP

GOEN CORPORATION

8 Ridgedale Avenue
Cedar Knolls, NJ 07927

973-267-4400 x 4020

Fax 973-267-5506

LEGAL DEPARTMENT

Ralph Fucetola III, JD

Corporate Counsel

ralph.fucetola@goengroup.com

Goen Technologies Corporation

Vitamerica Corporation

A. Goen Seminars Institute, Inc.

Seminar Helpers, L.L.C.

Nutramerica Corporation

Health Sciences Direct

Weight Loss Labs

John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

April 12, 2001

Dear Mr. Foret,

This letter is in response to your letter of March 7, 2001 (copy attached) which references certain 21 U.S.C. 343(r)(6) Structure and Function Claim Notices that we filed with the FDA Office of Special Nutritionals, dated January 31, 2001.

We are removing the five statements that you questioned from our product literature. I respectfully disagree that these may be considered "Drug Claims" since we do not intend to diagnose, treat, prevent, mitigate or cure disease by the use of these products. I can understand how they might be considered Health Claims, and in the case of one of the products, we have a Health Claim Petition pending for an additional claim we hope to be allowed to make in due course. We may do the same for some of the questioned claims.

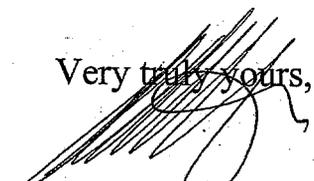
Further research of the literature provides us with substantiation for certain additional claims for our Trim Spa product and we have also revised the other Notices to reflect the removal of the questioned claims.

I therefore submit herewith copies of the revised Notices.

cc: Office of Special Nutritionals (HFS-450)

enc. (Lungevity™, Trim Spa™, CigSation™)

Very truly yours,



Ralph Fucetola III



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR - 7 2001

Mr. Ralph Fucetola III, JD
Goen Group/Goen Corporation
8 Ridgedale Avenue
Cedar Knolls, New Jersey 07927

Dear Mr. Fucetola:

This is in response to your letter of January 31, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that the Goen Group is making the following claims, among others, for the products below:

Lungevity™

“...soothes inflamed mucous membranes..”

Trim Spa

“...may have a normalizing effect on blood sugar levels..”

CigSation™

“Relieves congestion in the lungs”

“Reduces inflammation”

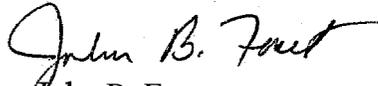
“Helps to accelerate healing”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Page Two - Mr. Ralph Fucetola III, JD

Please contact us if we may be of **further** assistance.

Sincerely,



John B. Foret

Director
Division of Compliance and Enforcement
Office of **Nutritional** Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA340

**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: Office of Special Nutritionals (HFS-450)
Center for Food' Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date of Original Notice: January 31, 2001 – Revision Date: April 12, 2001

Re: This Notice covers the following Brand(s): **Trim Spa™** **This revision deletes a claim not allowed in the Letter from the Division of Compliance and Enforcement dated March 7, 2001, adds additional claims and additional ingredients for which claims are made.**

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): the **Goen** Group, 8 Ridgedale Avenue, Cedar Knolls, New Jersey 07927 (includes **Goen** Technologies, Inc., Nutramerica Corporation and Vitamerica Corporation).

(ii) ~~The text~~ of the statement. ~~that is~~ being made: see attached Exhibit A.

(iii) ~~The name of the dietary~~ ingredient or supplement that is the subject of the statement: see attached Exhibit A.

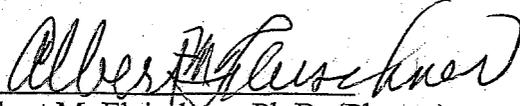
(iv) 'The ~~name~~ of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.

Prepared by:-
Ralph Fucetola, JD
Corporate Counsel


Albert M. Fleischer, Ph.D. (Pharm.)
Chief Operating Officer

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Statement ~~struck through~~ is deleted from this Revision – Additions are underlined.
Exhibit A

1. Brand Name(s) Included herein **Trim Spa**.
2. Dietary Ingredients or Supplements Included herein:
 - (a) Ma huang (ephedrine alkaloids) – 36 mg per 3 tablets
 - (b) Guarana Seed (caffeine) – 120 mg per 3 tablets
 - (c) Vanadium
 - (d) Black pepper
 - (e) Bladderwack kelp
 - (f) Spirulina
 - (g) Chromium dicotinate glycinate
 - (h) Glucosamine sulfate
 - (i) Inositol
 - (j) Peppermint
 - (k) Bitter Melon
 - (l) Rosemary Leaf
 - (m) L-Glutamine
 - (n) Cayenne
 - (o) Kola t
 - (p) Gymnema sylvestre and gurmarin, a constituent of gymnema sylvestre leaves
 - (q) Zinc
 - (r) Lipotropic Blend (lecithin, inositol, DL-methionine, choline bitartrate)
 - (s) bitter melon, rosemary leaf, peppermint black pepper, ginger, long pepper, kola nut, tangerine peel
 - (t) DL-phenylalanine
3. Statements Made with regard to each Ingredient (Same Order as #2):
 - (a) & (b) Helps to metabolize fat through thermogenesis. Maximizes your body's metabolism. You may experience a decrease in appetite. Ma huang and caffeine have a synergistic effect.
 - (c) Can work as an insulin mimic and is needed for cellular metabolism and thyroid function and may have a normalizing effect on blood sugar levels.
 - (d) Is a potent anti-oxidant that can enhance your immune system; also added for its antioxidant effects
 - (e) Regulates the thyroid gland; may be very helpful in reducing weight caused by thyroid troubles
 - (f) Assists in mineral absorption
 - (g) Can reduce cravings for sugar; helps prevent the fall of good cholesterol (HDL) during weight loss and increases insulin sensitivity; 300% more bioavailable than chromium picolinate; helps to, suppress sugar cravings and increases the rate at which you burn stored body fat for energy
 - (h) Allows your body to use up more glucose as energy, preventing it from being stored as fat
 - (i) Helps in transporting fats within the body
 - (j) Helps in many stomach problems such as irritable bowel syndrome, nausea, morning sickness, diarrhea, constipation and digestive distress
 - (k) Has been reported to stimulate digestion
 - (l) Relaxes the stomach
 - (m) Helps restore energy
 - (n) Rich in Vitamin C and considered a strong thermogenic
 - (o) Diminishes sensations of hunger and fatigue
 - (p) Tests and assays show that Gymnema sylvestre suppresses absorption of saccharides (sugars), preventing blood sugar elevation: (gurmarin) "can change your reaction to sweets"
 - (q) Helps stabilize eating behaviors
 - (r) Converts fats so they can be easily transported in the bloodstream
 - (s) "Several aid digestion"
 - (t) "Governs the release of a hormone that signals the brain to feel satisfied after a meal." – DL-phenylalanine governs the release of CCK, cholecystokinin.

In general, Trim Spa helps control your hunger throughout the day and at night.

**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 31, 2001. – Revision Date: April 12, 2001

Re: This Notice covers the following Brand(s): **Lungevity™** This revision deletes a claim not allowed in the Letter from the Division of Compliance and Enforcement dated March 7, 2001.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): the **Goen** Group, 8 Ridgedale Avenue, Cedar Knolls, New Jersey 07927.

(ii) The text of the statement that is being made: see attached Exhibit A.

~~(i) The name of the dietary ingredient or supplement that is the subject of the statement:~~
see attached Exhibit A.

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.

Prepared by:
Ralph Fucetola, JD
Corporate Attorney


Albert M. Fleischner, Ph.D.(Pharm.)
Chief Operating Officer

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 483(r)(6)

~~Deletion struck through.~~

Exhibit A

1. Brand Name(s) Included herein: **Lungevity.**

2. Dietary Ingredients or Supplements Included herein:
 - (a) N-Acetyl Cysteine (NAC)
 - (b) Vitamin A
 - (c) Vitamin B 6
 - (d) Deglycyrrhizinated Licorice
 - (e) Chamomile
 - (f) Slippery Elm
 - (g) Sarsaparilla
 - (h) Astragalus

3. **Statements Made with regard to each Ingredient (Same Order as #2):**
 - (a) NAC works to maintain glutathione and related antioxidant levels, has been shown to provide protection against free radicals, is an excellent mucolytic agent
 - (b) Vitamin A maintains the cells that line the respiratory tract and strengthens the immune system.
 - (c) Vitamin B 6, acting as a coenzyme, maintains immune system **function**
 - (d) Deglycyrrhizinated licorice root ~~soothes inflamed mucous membranes~~ and has expectorant properties
 - (e) Chamomile soothes the respiratory tract
 - (f) Slippery Elm contains mucilage which ~~has~~ demulcent, emollient and nutritive properties
 - (g) Sarsaparilla is used as a tonic
 - (h) Astragalus root acts as a tonic to **protect the immune system**

**SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA**

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date: January 31, 2001 – Revision Date: April 12, 2001

Re: This Notice covers the following Brand(s): **CigSation™**. **This revision deletes three claims not allowed in the Letter from the Division of Compliance and Enforcement dated March 7, 2001.**

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): the Goen Group, 8 Ridgedale Avenue, Cedar Knolls, New Jersey 07927 (includes Goen Technologies, Inc., Nutramerica Corporation and Vitamerica Corporation).

(ii) The text of the statement that is being made: see attached Exhibit A.

~~(iii) The name of the dietary ingredient or supplement that is the subject of the statement:~~
see attached Exhibit A.

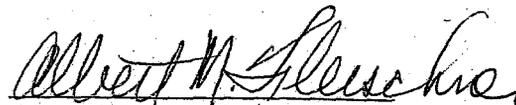
(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is **truthful** and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.

Prepared by:
Ralph Fucetola, JD
Corporate Attorney


Albert M. Fleischner, Ph.D.(Pharm.)
Chief Operating Officer

1st REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

Deletions are struck through.

Exhibit A

1. Brand Name(s) Included herein: **CigSation**

2. Dietary Ingredients or Supplements Included herein:

- (a) Lobelia
- (b) Fennel Seed
- (c) Blue Cohosh Root
- (d) Licorice Root
- (e) Black Walnut Husk
- (f) Wood Betony
- (g) Chamomile Flower
- (h) Gotu Kola Leaf Extract
- (i) Kava Kava Root
- (j) Peppermint
- (k) Sarsaparilla Root
- (l) Slippery Elm Bark
- (m) Valerian Root
- (n) Bayberry Fruit
- ~~(o) Myrrh~~
- ~~(p) Passion Flower~~
- (q) Ginger Root
- (r) Eucalyptus Leaf Oil

3. Statements Made with regard to the Ingredients:

<u>Claim</u>	<u>Ingredient</u>
(a) Relieves congestion in the lungs	a, b, c, d, e, f, g, h, i, j, k, l, m, n, o, p, q, r
(b) Relieves nervous tension	c, i, p
(c) Produces a calming effect	f, g, p, m
(d) Relieves fatigue and headache	f, n
(e) Reduces Inflammation	g
(f) Helps to accelerate healing	h
(g) Relieves stress	h
(h) Helps to soothe throat and lungs	d, l
(i) Promotes acetylcholine receptor satisfaction	a
(j) Helps relieve nausea	q